



NDA 19-508/S-034

Reliant Pharmaceuticals, Inc.
Attn: Fernando Marcella
110 Allen Road
Liberty Corner, NJ 17938

Dear Mr. Marcella:

Please refer to your supplemental new drug application dated July 29, 2005, received July 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Axid[®] (nizatidine) Capsules USP, 300 mg.

We acknowledge receipt of your submission dated August 24, 2005.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for a change in manufacturing and testing site for Axid[®] (nizatidine) Capsules USP, 300 mg. This supplement also provides for changes to the label. The majority of the label changes are identical to the changes made in your submission dated June 28, 2005 for Axid[®] (nizatidine) Capsules USP, 150 mg which was approved on December 23, 2005. An exception being the immediate container indicated as 1014M500 to include the appropriate dosage (300 mg) and pulvules count (see attachment.)

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 29, 2005.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Giuseppe Randazo, Consumer Safety Officer, at (301) 796 0918.

Sincerely,

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research
{See appended electronic signature page}

- Black
- PMS 153
- PMS 1245
- Non-varnish area inside

Label Size: 1 3/4" x 3 3/4"

Usual Adult Dose:
See accompanying literature for dosage.

Keep tightly closed.

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

Manufactured for:
Reliant Pharmaceuticals, Inc.
Liberty Corner, NJ 07938
by:
Patheon Pharmaceuticals Inc.
Cincinnati, OH 45237

NDC 65726-145-10

AXID®
(nizatidine)
Capsules, USP

300 mg

Rx only
30 PULVULES*

 **Reliant**

LOT
EXP

1014M500

65726 145 10 8

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Hasmukh Patel

1/26/2006 09:44:44 AM